IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

Glucotec, Inc., a South Carolina Corporation,	)	
Plaintiff,	)	C.A. No. 6:07-2995-HMH
vs.	)	
United States Department of Health and Human Services, Food and Drug Administration, Richard Roe, and John Doe,	)	**OPINION & ORDER**
Defendants.	)	

This matter is before the court on the United States Department of Health and Human Services' (DHHS) motion to dismiss pursuant to Rule 12(b)(1), (b)(4), and (b)(6) of the Federal Rules of Civil Procedure. After review, the court grants DHHS's motion to dismiss.

I. Factual and Procedural Background

Glucotec, Inc. ("Glucotec") filed the instant action on September 5, 2007, against DHHS, the United States Food and Drug Administration ("FDA"), and unnamed "medical service providers" Richard Roe ("Roe") and John Doe ("Doe"). (Compl. ¶¶ 1-3.) The complaint alleges that Roe and Doe violated the False Claims Act ("FCA"), 31 U.S.C. § 3729, by filing fraudulent Medicare claims seeking reimbursement from Centers for Medicare and Medicaid Services [("CMS")][1] for the use of devices that have not received approval from the FDA, "knowing in advance that disclosure of the use of the [d]evices would cause CMS to disallow" the claims.

[1] CMS is the agency within DHHS responsible for administering the Medicare program, as established by 42 U.S.C. § 1395 et seq., on behalf of the Secretary of Health and Human Services ("Secretary").

(Id. ¶ 24.) Specifically, Glucotec alleges that Roe and Doe have been initiating and receiving unlawful reimbursements for the use of blood glucose management devices trademarked under the names of "Glucostabilizer" and "Glucommander." (Id. ¶ 16, 18.) Further, according to Glucotec, Roe and Doe obtained these reimbursements by using "coding instructions" provided by the FDA "for inclusion of approved procedures and approved devices on claims forms to be submitted to CMS by health care providers." (Id. ¶ 12.) Glucotec states that these fraudulent claims are possible because health providers have used the coding instructions in a way that conceals the use of unapproved devices. (Id. ¶ 23.)

Based on the foregoing allegations, Glucotec seeks declaratory and injunctive relief against the FDA, "requiring modification of the system of Coding . . . to prevent further abuse by all Defendants (except the Defendant FDA) in the reimbursement by CMS of unapproved use of the Devices" and a writ of mandamus "requiring that the FDA enforce its lawful regulations, and further seek[s] denial of claims and disgorgement of monies received by [Roe and Doe] from CMS" for use of the unapproved devices. (Compl. ¶ 38.) In addition, Glucotec seeks monetary damages against Roe and Doe. (Id. ¶ 30.)

In its motion to dismiss, DHHS alleges that Glucotec is a South Carolina medical equipment company that markets and distributes blood glucose management and testing devices that compete with the Glucostabilizer and the Glucommander. (Def.'s Mem. Supp. Mot. Dismiss 3.) DHHS moves to dismiss the complaint on the grounds that the court lacks subject matter jurisdiction, Glucotec lacks standing, Glucotec fails to state a claim upon which relief can be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, and insufficient process pursuant to Rule 12(b)(4) of the Federal Rules of Civil Procedure. (Id., generally.)

DHHS filed the instant motion to dismiss on March 17, 2008. The Plaintiff did not file a response.

II. Discussion of Law

A. Standing

DHHS moves to dismiss the complaint under Rule 12(b)(1)[2] of the Federal Rules of Civil Procedure for "lack of jurisdiction over the subject matter." (Def.'s Mem. Supp. Mot. Dismiss 20-29.) Subject matter jurisdiction is limited by the "cases and controversies" requirement of Article III. Allen v. Wright, 468 U.S. 737, 750 (1984) (internal quotation marks omitted). "Doctrines like standing [and] . . . ripeness are simply subsets of Article III's command that the courts resolve disputes, rather than emit random advice." Bryant v. Cheney, 924 F.2d 525, 529 (4th Cir. 1991).

"With respect to the standing question, the Supreme Court . . . has carefully explained the irreducible constitutional minimum required." Dixon v. Edwards, 290 F.3d 699, 711 (4th Cir. 2002) (internal citations and quotation marks omitted). "First, [a plaintiff] must have suffered an injury in fact, i.e., an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." Id. (internal quotation marks omitted). "Second, [his] injuries must be fairly traceable to the actions of the [d]efendants, rather than the result of actions by some independent third party not before the

[2] Additionally, a standing argument can be properly made under Rule 12(b)(6) of the Federal Rules of Civil Procedure. However, "[a] challenge to the standing of a party raises the issue of justiciability and implicates the subject matter jurisdiction of a federal district court." Miller v. Hygrade Food Prods. Corp., 89 F. Supp. 2d 643, 646 (E.D. Pa. 2000). "Therefore, a motion to dismiss for want of standing is properly brought under Fed. R. Civ. P. 12(b)(1)." Id.

court." Id. "Third, it must be likely, as opposed to merely speculative, that [his] injuries will be redressed by a favorable decision." Id.

DHHS argues that Glucotec lacks Article III standing because it has neither alleged nor suffered an injury in fact, has failed to establish a causal connection between its unspecified injury and the conduct alleged in the complaint, and cannot establish that its injury would be redressed by a favorable decision. (Def.s' Mem. Supp. Mot. Dismiss 21.) The court agrees.

First, Glucotec has not alleged or suffered an injury in fact. In the complaint, the only harm alleged by Glucotec is "as a taxpayer and citizen of the United States, in that the costs of administration and payments under the Medicare program of the United States have been increased, to the detriment of the Plaintiff." (Compl. ¶ 29.) "It has long been established, however, that the payment of taxes is generally not enough to establish standing to challenge an action taken by the Federal Government." Hein v. Freedom from Religion Found., Inc., 127 S. Ct. 2553, 2559 (U.S. 2007). This is because "the interests of a taxpayer in the moneys of the federal treasury are too indeterminable, remote, uncertain and indirect to furnish a basis for an appeal to the preventive powers of the Court over their manner of expenditure." Doremus v. Bd. of Educ. of Hawthorne, 342 U.S. 429, 433 (1952).

The Supreme Court has recognized a "narrow exception" to the general rule if a plaintiff alleges a violation of the Establishment Clause. Hein, 127 S. Ct. 2564. However, that exception clearly does not apply to the instant case. Therefore, Glucotec's status as a taxpayer is insufficient to confer Article III standing on it to bring the instant action.

Second, Glucotec has failed to establish the necessary causal connection between its alleged injury and the conduct complained of in the complaint. (Def.'s Mem. Supp. Mot.

Dismiss 22.) The Medicare Act restricts the scope of benefits to payments for "expenses incurred for items or services which . . . are . . . reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A) (2003). "The Medicare Act neither requires nor specifically authorizes the Secretary to deny reimbursement for medical devices based upon FDA approval for marketing." Cedars-Sinai Med. Ctr. v. Shalala, 939 F. Supp. 1457, 1465 (C.D. Cal. 1996). Further, "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which []he implements h[is] decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." Heckler v. Ringer, 466 U.S. 602, 617 (1984) (citing 42 U.S.C. § 1395ff(a)). Therefore, even if Glucotec could establish an injury, it would lack standing because CMS has the discretion to provide Medicare coverage for the unapproved devices if it determines that the devices are reasonable and necessary. Glucotec has not alleged that CMS has a nondiscretionary duty to deny coverage of the unapproved devices, and consequently, Glucotec has failed to establish a causal connection between its alleged injury and any improper action or omission on the part of the FDA or CMS.

Finally, Glucotec's alleged injuries are not likely to be redressed by a favorable decision in the instant case. In its complaint, Glucotec seeks "declaratory and injunctive relief against the Defendant FDA, requiring modification of the system of Coding promulgated by the said Defendant FDA to prevent further abuse by all Defendants (except the Defendant FDA) in the reimbursement by CMS of unapproved use of the Devices." (Compl. ¶ 38.) Glucotec has failed to identify the particular regulatory provisions it seeks to modify or the nature of the modifications, making injunctive or declaratory relief virtually impossible. Similarly, Glucotec

seeks "[m]andamus . . . requiring that the FDA enforce its lawful regulations, and further seek[s] denial of claims and disgorgement of monies received by Richard Roe and John Doe from CMS as Medical Expenses using the Devices." (Id.) Because Glucotec has failed to identify any specific providers that have allegedly submitted false claims and received improper payments, the mandamus relief sought is also virtually impossible to grant or to result in any meaningful remedy.

Further, the decision to investigate alleged violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") and pursue enforcement actions is committed to the FDA's discretion, and is not subject to judicial review. See Heckler v. Chaney, 470 U.S. 821, 831, 835-838 (1985); Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 950 (D.C. Cir. 1987) ("FDA employs complete discretion not to employ the enforcement provisions of the FDC[A], and those decisions are not subject to judicial review."). In addition, CMS's determination as to whether Medicare reimbursement for an item or service is reasonable and necessary is within the agency's discretion, and as stated above, the Medicare Act does not require the Secretary to deny reimbursement for medical devices based upon FDA approval for marketing. See Cedars-Sinai Med. Ctr., 939 F. Supp. at 1465; Ringer, 466 U.S. at 617. CMS has not determined that the Glucommander and the Glucostabilizer are not reasonable and necessary. Therefore, these agency actions or omissions are not subject to the injunctive, declaratory, and mandamus relief sought by Glucotec. Consequently, Glucotec's alleged injuries are not likely to be redressable by a favorable decision in the instant action. Based on the foregoing, Glucotec lacks Article III standing and Glucotec's claims against the FDA and DHHS are dismissed for lack of subject matter jurisdiction.

B. Rule 12(b)(4) and (b)(6)

In addition, DHHS moves to dismiss Glucotec's complaint based on insufficient process and failure to state a claim upon which relief can be granted. (Def.'s Mem. Supp. Mot. Dismiss 29-34.) Although it is not explicit in the complaint, out of an abundance of caution, the court finds that to the extent Glucotec intended to file a qui tam action under the FCA,[3] the case is dismissed pursuant to Rule 12(b)(4) of the Federal Rules of Civil Procedure for insufficient process. Glucotec did not file its complaint in conformity with the requirements of the FCA. The complaint was not properly served on the Government, the complaint was not filed under seal, and a written disclosure of all material evidence and information in Glucotec's possession was not provided to the Government. See 31 U.S.C. § 3730(b)(2) (2003).

Further, in the complaint, Glucotec alleges that "Richard Roe and John Doe, acting as medical service providers, have made one or more claims to the United States government that are false or fraudulent, knowing of the falsity or fraudulent nature, and in doing so have sought, and continue to seek, payments from the United States Treasury." (Compl. ¶ 27.) This general allegation is insufficient to state a claim for fraud pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. See Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 783-84 (4th Cir. 1999) (noting that claims of fraud under the FCA must be pled "with particularity" including "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby"). Therefore, to the extent Glucotec intended to file a qui tam action under the FCA against Roe and Doe, this claim is dismissed for insufficient process and failure to state a claim upon which relief can be granted

[3] See 31 U.S.C. § 3730(b).

pursuant to Rule 12(b)(4) and (b)(6) of the Federal Rules of Civil Procedure. Based on the foregoing, DHHS's motion to dismiss is granted.[4]

It is therefore

ORDERED that DHHS's motion to dismiss, docket number 13, is granted.

IT IS SO ORDERED.

s/Henry M. Herlong, Jr.
United States District Judge

Greenville, South Carolina
April 11, 2008

[4] Because the court is granting DHHS's motion to dismiss based on standing and Rule 12, the court declines to address DHHS's remaining grounds for dismissal.